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09/745,108	12/20/2000	William J. Bertrand	5074X-000003/US/COA	7744
27572                      7590                      02/15/2012 HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303				
EXAMINER				
PRICE, NATHAN R				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

09/745,108

**Applicant(s)**

BERTRAND ET AL.

**Examiner**

NATHAN R. PRICE

**Art Unit**

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 July 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 5) ☒ Claim(s) 10-39 is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 10-39 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 23 March 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

1. This office action is responsive to the amendment filed on May 24, 2004 (same claims filed again on July 8, 2011). As directed by the amendment: no claims have been amended, claims 1-10 been cancelled, and new claims 10-39 have been added. Thus, claims 10-39 are presently pending in this application.

### ***Drawings***

2. The drawings were received on March 23, 2001. These drawings are not acceptable. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). Appropriate correction is required.

### ***Specification***

3. The disclosure is objected to because of the following informalities: pg. 10, ln. 204 states "a indicator central indicator central" which appears to be mistaken duplication, and uses "a" instead of "an". Applicant should review the entirety of the specification for errors.

Appropriate correction is required.

### ***35 USC § 112, 6<sup>th</sup> Paragraph Notes***

4. Claims 10-18 recite the limitation "means for coupling the indicator...." This limitation is worded as a means plus function limitation. However, the limitation is modified by sufficient structure for performing the claimed function ("including a deck

having an outer edge and a locator central opening extending entirely through the deck"). Therefore, this limitation does not invoke 35 U.S.C. 112, 6th paragraph.

5. Claim 22 recites the limitation "the means for coupling". This limitation is worded as a means plus function limitation. However, the limitation is modified by sufficient structure for performing the claimed function ("further includes a substantially cylindrical tube having an inner surface, the outer edge of the deck being attached to the inner surface of the tube", in addition to the structure from parent claim 10 noted above). Therefore, this limitation does not invoke 35 U.S.C. 112, 6th paragraph.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 10-15 and 17-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Regarding claim 10, the limitation "the locator central opening is capable of **overlying the conforming to the** tactile physical characteristic" (emphasis added) is indefinite. It is not clear if this is intended to claim that the locator both overlays and conforms to, or whether one of these two modifiers was included in error or they are intended to be recited in the alternative.

9. Regarding claims 11, 13, and 15, claim elements "means for magnetically coupling with the magnet in a valve to indicate a current valve setting", "means for indicating the current setting of the valve", and "means for physically and removably

coupling the indicator tool to the locator tool so that the indicator tool is aligned with the locator tool" are limitations that invoke 35 U.S.C. 112, sixth paragraph. However, the written description fails to clearly link or associate the disclosed structures, materials, or acts to the claimed functions such that one of ordinary skill in the art would recognize what structures, materials, or acts perform the claimed functions.

Applicant may:

- (a) Amend the claim so that the claim limitation will no longer be interpreted as a limitation under 35 U.S.C. 112, sixth paragraph; or
- (b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or
- (c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification and linked or associated to the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

For the purposes of examination, these limitations are not interpreted to invoke 35 U.S.C. 112, 6<sup>th</sup> paragraph.

10. Regarding claims 12, 14, 15, and 18, claim elements "means for magnetically coupling with the magnet in the valve to move the magnet to change the current setting of the valve", "means for moving the magnet in the valve to move the magnet to change the current setting of the valve", and "means for coupling the means for moving the magnet to the locator tool..." are limitations that invoke 35 U.S.C. 112, sixth paragraph.

However, the written description fails to clearly link or associate the disclosed structures, materials, or acts to the claimed functions such that one of ordinary skill in the art would recognize what structures, materials, or acts perform the claimed functions.

Applicant may:

- (a) Amend the claim so that the claim limitation will no longer be interpreted as a limitation under 35 U.S.C. 112, sixth paragraph; or
- (b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or
- (c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification and linked or associated to the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

For the purposes of examination, these limitations are not interpreted to invoke 35 U.S.C. 112, 6<sup>th</sup> paragraph

11. Further regarding claims 11, 13, and 15, the limitation “means for indicating the current setting of the valve”, as worded, appears to encompass the same structure as the previously recited “means for magnetically coupling with the magnet in a valve **to indicate a current setting of the valve**” (emphasis added). In other words, it would appear that both means plus function limitations are directed to the same structure as the encompassed structure for each is recited to perform the same function. The

specification, as noted above, also fails to link either means plus function limitation to disclosed structure for performing the claimed function. It is not clear what structure would be encompassed by either limitation, much less how the two structures would differ. Therefore, for the purposes of examination, these two limitations are interpreted to encompass the same structure.

12. Further regarding claims 12, 14, and 15, the limitation "means for moving the magnet in the valve to move the magnet to change the current setting of the valve" as worded, appears to encompass the same structure as the previously recited "means for magnetically coupling with the magnet in the valve **to move the magnet to change the current setting of the valve**" (emphasis added). In other words, it would appear that both means plus function limitations are directed to the same structure as the encompassed structure for each is recited to perform the same function. The specification, as noted above, also fails to link either means plus function limitation to disclosed structure for performing the claimed function. It is not clear what structure would be encompassed by either limitation, much less how the two structures would differ. Therefore, for the purposes of examination, these two limitations are interpreted to encompass the same structure.

13. Further regarding claims 12, 14, and 15, the limitation "means for moving the magnet in the valve to move the magnet" contains redundant wording. It is unclear what is implied by reciting that the means is "for moving the magnet" and "to move the magnet".

14. Regarding claim 17, the limitations "providing a trocar tool having an indicator...specific orientation of the valve" is recited twice. It is unclear whether two different structures are being recited or whether this duplication was included in error. There is also a period after "means for coupling with." in line 6.

15. Further regarding claim 18, there is a period after "specific orientation of the valve." in line 7.

16. Regarding claim 24, the claim elements "means for coupling the means for moving the magnet..." and "means for removably constraining the movement of the means for moving the magnet" are limitations that invoke 35 U.S.C. 112, sixth paragraph. However, the written description fails to clearly link or associate the disclosed structures, materials, or acts to the claimed functions such that one of ordinary skill in the art would recognize what structures, materials, or acts perform the claimed functions.

Applicant may:

(a) Amend the claim so that the claim limitation will no longer be interpreted as a limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or

(c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification and linked or associated to the



claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

17. Further regarding claim 24, the limitation "the means for coupling the means for moving the magnet to the locator tool" lacks antecedent basis. This element is not recited in a parent claim, and it is not clear to what structure recited in claim 12 this limitation may refer. The limitation "the movement" also lacks antecedent basis.

18. Claims 19-23 and 25-39 are rejected as they depend from a claim rejected under this statute.

***Claim Rejections - 35 USC § 102***

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. Claims 10, 11, 13, 16, 17, 19-23, and 25-29, as best understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Hakim et al. (US 4608992).

21. Regarding claims 10, 11, 13, 16, 17, 19-23, and 25-29, as best understood, Hakim et al. teaches a locator tool (structure of fig. 1) and an indicator tool 74 for detection of information about an implanted shunt valve (embodiment described in col. 5, ln. 12-15). Hakim teaches a system for aligning the locator tool with a subcutaneously implanted shunt valve, wherein the implanted valve physically protrudes into a recess in the locator tool thus aligning the two components (see fig. 2; col. 4, ln. 14-17). Specifically, Hakim teaches a deck 10, a visual arrow indicator 74 on the deck,

and a cylindrical tube within deck attached (structure of 10). Further, Hakim teaches that the deck has a locator central opening 26 extending entirely through the deck (see fig. 1; the opening 26 extends entirely from one side to the other through the device). Hakim et al. discloses the indicator tool 74 comprising means for magnetically coupling with the magnet in a valve to indicate current setting of the valve (ferromagnetic crystals which collect into a shape as shown in fig. 5; col. 4, ln. 8-11; col. 5, ln. 36-42), and means for coupling the indicator tool with the locator tool (shown coupled together in fig. 2; col. 4, ln. 8-14). Hakim et al. teaches the steps of providing a locator tool as claimed (see structure cited above), palpating the valve to determine its physical characteristics (via protrusion 24; col. 3, ln. 5; fig. 2); setting the locator tool over a portion of the valve to mechanically couple to the tactile physical characteristic 24 by placing the central opening over the characteristic (col. 4, ln. 6-7; col. 6, ln. 26-27) so that space between is minimized (see minimized space between shown in fig. 2), and coupling the indicator tool to the locator tool (shown coupled in fig. 1 and 2).

22. Claims 12 and 24, as best understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Hooven (US 4676772).

23. Regarding claims 12 and 24, as best understood, Hooven discloses an adjustment tool ("tool" including magnet 75; col. 6, ln. 6-10) comprising means for magnetically coupling with and changing the setting of a valve magnet (magnetic element 75), and a locator tool (fig. 3), and means for coupling the means for moving to the locator tool so that the locator tool constrains the movement of the means for moving (magnetic element 72 would form a magnetic couple with the magnet when the

magnet tool is placed over the locator tool over 72; the adjustment tool being constrained from moving distally towards the valve by the presence of the locator tool).

***Claim Rejections - 35 USC § 103***

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

25. Claims 14, 15, 18, and 30-39, as best understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Hakim et al. in view of Hooven.

26. Regarding claims 14, 15, 18, and 30-39, as best understood, Hakim et al. discloses the apparatus as claimed (see above) except for the adjustment tool and using the adjustment tool as claimed. However, Hooven teaches an adjustment tool ("tool" including magnet 75; col. 6, ln. 6-10) and using it to set the device setting (col. 6, ln. 6-35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the adjustment tool of Hooven with the device of Hakim et al. in order to adjust the valve setting, since the use of a magnet to adjust the valve setting is well-known (as taught by Hooven) and since a magnetic adjustment would be most logical in the instant case (i.e. a subcutaneously implanted shunt valve with moveable, magnetic valve components detected to indicate the setting).

***Response to Arguments***

27. Applicant's arguments filed May 24, 2004 have been fully considered but they are not persuasive.

28. The majority of Applicant's arguments are drawn to a lack of limitations in the prior art. However, with specific reference to independent device claims 10-15, the limitations that Applicant argues are not present in the prior art are not positively recited in the instant application. These limitations, in the form that they may be present in the claims, are presented as functional limitations. For example, in claim 12, everything between "an adjustment tool" in line 1 and "the adjustment tool comprising" in line 15 is functional. The other independent claims contain limitations phrased similarly in a functional way. Furthermore, these limitations occur in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hira*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Thus, these claims do not positively recite the implantable valve. The structure cited need only be capable of functioning with such a valve. Examiner maintains that the structure disclosed, as cited above, is capable of functioning with such a valve. Regarding the method claims 16, 17, and 18 (also applicable to device claims), Examiner maintains that Hakim et al. specifically recites a valve. Applicant's arguments on page 16 of the Remarks about the type of valve are replete with features that are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

29. Applicant also argues that Hooven does not teach certain features, including the "locator central opening" as claimed. However, Hooven is not relied upon for this element. As noted in the rejections above, Hakim et al. is relied upon for teaching this element.

### ***Conclusion***

30. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN R. PRICE whose telephone number is (571)270-5421. The examiner can normally be reached on Monday-Thursday, 9:00 a.m. - 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. R. P./  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art  
Unit 3763